



This document is scheduled to be published in the Federal Register on 09/25/2014 and available online at <http://federalregister.gov/a/2014-22770>, and on [FDsys.gov](http://FDsys.gov)

## OFFICE OF SCIENCE AND TECHNOLOGY POLICY

### Notice Response to Comments and Notice of Final Action Regarding the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*

**SUMMARY:** On February 22, 2013, the Office of Science and Technology Policy (OSTP) published a 60-day public notice in the *Federal Register* (*Federal Register* Volume 78, Number 36, Docket No. 2013-04127) to invite public comment on the proposed *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (hereafter, *Policy for Institutional DURC Oversight* or *Policy*). This Notice responds to comments received during this 60-day public notice, sets forth final changes to the *Policy for Institutional DURC Oversight*, and implements the final *Policy for Institutional DURC Oversight*. The *Policy for Institutional DURC Oversight* will be updated, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, and global health specialists and announced in the *Federal Register* and at <http://www.phe.gov/s3/dualuse>.

**DATE(S):** *Policy release date:* September 24, 2014. *Effective date:* September 24, 2015. The 12-month period between release and effective date will allow institutions and USG funding agencies subject to this Policy to establish the procedures necessary to comply with this Policy. Certification of compliance will be required of institutions to which the Policy applies, as defined in Section 6.1, at the time of seeking funding, but no sooner than the effective date of the Policy.

### ADDRESSES:

**FOR FURTHER INFORMATION CONTACT:** Dr. Andrew M. Hebbeler, Assistant Director for Biological and Chemical Threats, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue, Washington, DC 20504, [DURCpolicy@ostp.gov](mailto:DURCpolicy@ostp.gov).

**SUPPLEMENTARY INFORMATION:** The *Policy for Institutional Oversight of Life Sciences DURC* is available on the U.S. Department of Health and Human Services Science Safety Security (S3) Web site: <http://www.phe.gov/s3/dualuse>.

## **Background**

Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, and the environment; materiel<sup>1</sup>; and national security. While life sciences research has and will continue to yield benefits, no research comes without risk. Generally speaking, the risks associated with the conduct of life sciences research, such as accidental exposure of personnel or the environment to a pathogen or toxin, are addressed by existing and complementary statutes, regulations, and guidelines<sup>2</sup> that ensure that life sciences research is conducted safely and securely.

However, despite the doubtless value and benefits of the outcomes of scientific research, there are certain types of legitimately-conducted research that generate knowledge, information, products, or technologies that could also be intentionally utilized for harmful purposes. Such research is deemed to be “dual use research.” Within the life sciences, there exists a subset of dual use research that merits *particular* attention due to the magnitude of the potential consequences of its misuse or misapplication.

---

<sup>1</sup> Materiel includes food, water, equipment, supplies, or material of any kind.

<sup>2</sup> E.g., the select agent regulations ([42 CFR Part 73](#), [9 CFR Part 121](#), and [7 CFR Part 331](#)); [NIH Guidelines on Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) (NIH Guidelines); and [Biosafety in Microbiological and Biomedical Laboratories](#) (BMBL), 5th Edition.

This research is called dual use research *of concern* (DURC) and is defined in the *Policy for Institutional DURC Oversight* as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Funders of life sciences research and the institutions and scientists who conduct this research have a shared responsibility for oversight of DURC and for promoting its responsible conduct and communication. A comprehensive oversight system for DURC includes the policies, practices, and procedures put in place to ensure DURC is identified and risk mitigation measures are implemented, where applicable, and such a system must include both Federal and institutional oversight processes. Institutional oversight of DURC is a critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC.

The *Policy for Institutional DURC Oversight* is one of two USG policies that apply to the oversight of life sciences research with dual use potential. The other policy is the *USG Policy for Oversight of Life Sciences Dual Use Research of Concern*, issued on March 29, 2012 and hereafter referred to as the *March 2012 DURC Policy*.<sup>3</sup> The *March 2012 DURC Policy* sets forth a process of regular Federal review of USG-funded or -conducted research and requires Federal agencies that fund or sponsor life sciences research to identify DURC and evaluate this research for possible risks, as well as benefits, and to ensure that risks are appropriately managed and benefits realized. The *Policy for*

---

<sup>3</sup> The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (*March 2012 DURC Policy*), March 29, 2012, [www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf](http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf).

*Institutional DURC Oversight* complements the *March 2012 DURC Policy* by establishing review procedures and oversight requirements for the same scope of life sciences research at the institutions that receive Federal funding for such research. Together, the two policies work to engage the life sciences research community and the Federal departments and agencies that fund such research in a shared commitment to address the risk that knowledge, information, products, or technologies generated from life sciences research could be used for harm. In addition, the *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy* emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.<sup>4</sup>

### **Text of the Final *Policy for Institutional DURC Oversight***

The final *Policy for Institutional DURC Oversight* is available on the U.S. Department of Health and Human Services Science Safety Security (S3) website: [www.phe.gov/s3/dualuse](http://www.phe.gov/s3/dualuse).

### **Companion Guide to the USG Policies for Oversight of Life Sciences Dual Use Research of Concern**

The USG has developed a guide to assist in implementation of both the final *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*, entitled *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the USG Policies for Oversight of Life Sciences Dual Use Research of Concern* (hereafter, *Companion Guide*). The comments received in response to the proposed Policy were taken into consideration in developing the guidance and other information that are included in the *Companion*

---

<sup>4</sup> The *March 2012 DURC Policy* and the final *Policy for Institutional DURC Oversight* are complemented by extant laws and treaties (e.g., United States Code Title 18 Section 175 and the Biological and Toxin Weapons Convention) that prohibit the development, production, acquisition, or stockpiling of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and that prohibit the use of biological agents and toxins as weapons.

*Guide*. Use of the *Companion Guide* by PIs, institutions, and Institutional Review Entities (IREs) is voluntary. The *Companion Guide* will be considered for revisions as experience in implementing the final *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy* and in utilizing the tools included in the *Companion Guide* accumulates. This review will be carried out periodically as needed.

The *Companion Guide* is available on the U.S. Department of Health and Human Services Science Safety Security (S3) Web site: <http://www.phe.gov/s3/dualuse/>.

### **Training and Education on DURC and its Oversight**

The USG and individual Federal funding agencies are developing training and education resources to assist institutions and PIs in meeting the requirements of Sections 7.2.G and 7.1.E, respectively, of the final *Policy for Institutional DURC Oversight*. These resources will be made available on the U.S. Government Science Safety Security (S3) website, <http://www.phe.gov/s3/dualuse/>. The training and educational resources will be considered for revisions as experience in such training accumulates. This review will be carried out periodically as needed.

For institutions subject to the final Policy, the USG anticipates that the requirements for education and training on DURC will be met by the effective date of the Policy or at the point of providing certification of compliance to a Federal funding agency or agencies, as described in Section 7.2.L of the final Policy. The twelve-month time frame between the release of the final Policy and its effective date was deemed sufficient to allow institutions to perform outreach and training for investigators whose research will now be subject to the *Policy for Institutional DURC Oversight*.

### **Summary of Public Comments & Revisions Reflected in the Final Policy**

On February 22, 2013, the Office of Science and Technology Policy (OSTP) published a 60-day public notice in the *Federal Register* (*Federal Register* Volume 78, Number 36, Docket No. 2013-04127)<sup>5</sup> to invite public comment on a proposed draft of the *Policy for Institutional DURC Oversight*, and to gather specific comments on 16 questions relating to the Policy and its possible implementation.<sup>6</sup> In addition to assisting in the development of the final Policy, the comments were helpful in identifying and developing materials that are designed to aid institutions in the implementation of the final *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*. By the end of the 60-day comment period, OSTP received 38 responding commentaries on the proposed Policy from 27 entities, described below. The majority of the responses (20) represented the viewpoints of departments and offices of 16 different research institutions: 11 universities, three teaching hospitals, one non-profit owning two of the commenting teaching hospitals, and one public health reference laboratory. Six professional associations and one citizens' group each submitted one response. Eleven of the responses were submitted by private citizens, eight of whom identified themselves as researchers or scientists.

The following paragraphs review the specific comments received on each section of the final Policy; the USG's response to those comments; and the revisions and additions included in the final Policy.

## **Section 1. Introduction**

The introductory text of the final *Policy for Institutional DURC Oversight* states that the USG will update the Policy, as warranted, based on feedback on implementation of the final Policy, evaluation of

---

<sup>5</sup> "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern; Notice, Request for Comment," 78 *Federal Register* 36 (22 February 2013), pp 12369 -12372, [federalregister.gov/a/2013-04127](https://www.federalregister.gov/a/2013-04127).

<sup>6</sup> *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Policy for Institutional DURC Oversight)*, February 21, 2013, [www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf](https://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf).

the Policy's impact, and assessment of the advantages and disadvantages of expanding the scope of the Policy. In the final Policy, the introductory statement was revised to include that the USG will update the components outlined in the final Policy and the *March 2012 DURC Policy*, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, and global health specialists.

The introduction in the final Policy, as well as a short statement in Section 6.1 (Applicability), include revisions to clarify that while institutions may, as they deem appropriate, expand their internal oversight to life sciences research outside the scope of the final Policy, such an expansion of scope by the institution would not be subject to oversight as articulated in the final Policy.

#### **Section 4. Definitions**

Two new definitions are provided in the final *Policy for Institutional DURC Oversight*. The first, a definition of "to certify," which means to attest to the USG that an institution subject to this Policy will comply with all aspects of this Policy. A definition has also been provided for "Principal Investigator" (PI). For the purposes of the Policy, a PI is an individual who is designated by the research institution to direct a project or program and who is responsible to the funding agency or the research institution for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project within a single or multiple institutions.

Two definitions have been modified. The definition for the Institutional Contact for Dual Use Research (ICDUR) was revised to clarify that the person serving in this capacity should function as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and

the relevant USG funding agency. The definition of “life sciences” was also revised to align with the definition of the same term in the *March 2012 DURC Policy*, i.e., for the purposes of the final Policy, “life sciences” includes the discipline of aerobiology.

## **Section 5. Policy Statement**

Section 5.A of the final *Policy for Institutional DURC Oversight* includes slight revisions that clarify that life sciences research that meets the scope specified in Section 6.2 of the final Policy is subject to Federal oversight through the *March 2012 DURC Policy* as well as the institutional oversight set forth in the final Policy.

## **Section 6.1 Applicability**

In the final *Policy for Institutional DURC Oversight*, the last paragraph of the applicability section was revised to clarify that life sciences research institutions that conduct or sponsor research that is within the scope of the Policy but receive no USG funds in support of life sciences research are not required to adhere to the oversight requirements of the final Policy. These institutions are, however, strongly encouraged to implement internal oversight procedures consistent with the culture of shared responsibility underpinning the Policy. As noted in the Introduction to the final Policy, institutions may also, as they deem appropriate, expand their internal oversight to life sciences research outside the scope of the final Policy; however such an expansion of scope by the institution would not be subject to oversight as articulated in the final Policy.

The final Policy also reflects the relocation of the paragraph regarding compliance with the Policy from this section to a new section, Section 6.3.

## **Section 6.2. Scope of Research Requiring Oversight**

The scope of the proposed *Policy for Institutional DURC Oversight* includes research that directly involves non-attenuated forms of the 15 agents or toxins listed in Section 6.2.1 of the final Policy, including the use of botulinum toxin at any quantity, and which also produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in Section 6.2.2 of the final Policy. Comments on the proposed Policy were specifically requested regarding the appropriateness of the scope of the Policy, including whether the scope should be expanded to all select agents, microbes, or all life sciences; what factors should be considered in determining a final or revised scope; what criteria might be used to determine what research should or should not be subject to oversight; and what effects such an expansion might have on the ability to conduct research. In addition, comments were invited on whether the scope of the proposed Policy should be expanded to include the use of any of the listed 15 agents or toxins in attenuated forms; the use of the genes from any of the listed 15 agents or toxins; *in silico* experiments (e.g., modeling experiments, bioinformatics approaches) involving the biology of the listed 15 agents or toxins; or research related to the public, animal, and agricultural health impact of any of the 15 listed agents or toxins (e.g., modeling the effects of a toxin, developing new methods to deliver a vaccine, developing surveillance mechanisms for a listed agent).

Eighteen comments were received on the topic of expanding the scope of the proposed Policy. Eleven comments favored the proposed scope or narrowing the proposed scope, while seven comments favored expansion of the proposed scope. Eight of the comments cited a negative impact on research should the scope be expanded, while nine comments made no mention of effects on the ability to conduct the research. One institution that already conducts DURC reviews of all recombinant DNA and BSL-3 research cited no additional burden as a result of an expanded scope for its review process. In general,

those in favor of scope expansion expressed satisfaction with the current scope, with the understanding that expansion may occur in the future.

Thirteen comments were received in response to the more specific question on modifications to the scope. Three comments recommended no expansion or modification to the scope of the Policy, while two considered the scope appropriate at the current time but acknowledged that future developments may warrant changes. Five comments suggested that attenuated forms of agents should be considered for inclusion in the scope of the Policy if there is sufficient justification. Three comments expressed support for expanding the scope to include genes known to increase pathogenicity, virulence, or infectivity; however, one of these comments proposed limiting the source of these genes to any of the listed agents, while the other two comments noted that any genes known to increase these characteristics should be included in the scope. Two comments supported expansion of the scope to include consideration of *in silico* experiments. Two other comments received on this topic requested additional guidance on review of these types of studies in the event of an expansion of the Policy's scope. One comment suggested that the scope of the Policy could permit flexibility beyond a specific list of pathogens by limiting the scope to only the seven identified categories of experimental effects (Sec 6.2.2) and thus the review process would involve evaluating the dual use implications of all research meeting one or more of these seven categories.

Because institutional oversight of DURC will be a new undertaking for many institutions, the USG has maintained the scope of the final Policy as a well-defined subset of life sciences research that involves 15 agents<sup>7</sup> and seven categories of experiments. Of note, the final Policy is intended to apply

---

<sup>7</sup> The 15 agents and toxins listed in the *Policy for Institutional DURC Oversight* are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of the *Policy for Institutional DURC Oversight* or the *March 2012 DURC Policy*.

only to research that directly involves non-attenuated<sup>8</sup> forms of the 15 agents. After implementation of the final Policy, the USG will assess the advantages and disadvantages of expanding the scope of the Policy to encompass additional agents and/or categories of experiments and will update the Policy, as warranted.

### **Section 6.3. Compliance**

Ten comments were received regarding the issue of compliance with the proposed *Policy for Institutional DURC Oversight*. Six of these comments noted that the proposed Policy contained limited information on compliance or its implementation or enforcement at institutions and Federal agencies. In addition, three of the comments indicated confusion regarding the role of the Institutional Review Entity (IRE) in ensuring compliance with the Policy. To address confusion and concerns over the responsibilities for compliance on both the part of the institution and the Federal funding agency, language regarding compliance with the Policy has been moved to a separate section (Section 6.3) and reflects revisions that clarify that any suspension, limitation, or termination of USG funding or loss of future USG funding opportunities due to noncompliance with the final Policy will be consistent with existing regulations and policies governing USG-funded research and may subject the institution to other potential penalties under applicable laws and regulations.

Regarding the role of the IRE in ensuring compliance at the institution, Section 7.2.H of the final Policy includes revisions intended to clarify that it is the institution, not the IRE, that is responsible for institutional compliance with the Policy.

---

<sup>8</sup> The only forms of the agents or toxins listed in Section 6.2.1 of the final *Policy for Institutional DURC Oversight* that, for the purposes of the Policy, are considered by the USG to be attenuated and therefore not subject to the requirements of the Policy, can be found on the Select Agent and Toxin Exclusions list under “Attenuated Strains of HHS and USDA Select Agents and Toxins” at: <http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html>.

## **Section 7. Organizational Framework for Oversight of DURC**

The figure in Section 7 has been modified to correspond to changes and revisions described below.

### **Section 7.1. Responsibilities of Principal Investigators**

The proposed *Policy for Institutional DURC Oversight* required PIs to refer any research involving one or more of the 15 listed agents to an IRE, which would then determine whether the research can be reasonably anticipated to produce any of the seven effects, and if so, whether that research meets the definition of DURC.

Comments were solicited on whether it is preferable to require PIs to determine whether their research involves one or more of the listed agents as well as determine whether any of his or her research involving one or more of the listed agents can be reasonably anticipated to produce any of the listed effects before referring the research to the IRE. Fourteen comments were received on this topic. Nine of the comments were supportive of a review process that would require the PI to assess his or her research for both use of one or more the listed agents and the applicability of the listed experiments. Furthermore, nine comments indicated that the assessment of the applicability of the listed experimental effects should be conducted by both the PIs and the IRE.

Comments from two institutions with extant review systems for dual use research indicated that their review processes already require that PIs assess their research for the listed experimental effects and participate in discussions of the risks and benefits of the research. These institutions noted that the increased involvement of the PI in the review process is beneficial for both the PI and the institution

because it promotes a common understanding of DURC, informs the institution of instances when training on DURC might be needed, strengthens the review, enhances collaboration, and improves compliance. Two other comments in support of the expansion of the PI's role noted that because of the Policy's requirements for ongoing review by PIs, the expectation of PIs to assess the applicability of the listed effects at the outset of the research is both reasonable and beneficial. Four comments opposed expanding the PI's role regarding review of research for experimental effects. These comments cited concerns about the subjective nature of the determination, and that PIs did not have sufficient expertise for the assessment. In response to these comments, Section 7.1.A of the final Policy includes revisions that require PIs initiating or conducting research with one or more of the listed agents to also review the research for the presence or anticipation of any of the listed experimental effects. Section 7.1.B also includes revisions that indicate that the PI must work with the IRE to assess the risks and benefits of the research as well as to develop the risk mitigation measures for any research determined to be DURC. For consistency, similar changes were made to the description of the responsibilities of institutions (Section 7.2.B.iii).

Comments were also solicited on whether research that has undergone institutional dual use review, but has been determined by the IRE to not meet the definition of DURC, should be monitored for emerging DURC issues. While the proposed *Policy for Institutional DURC Oversight* did not place any periodicity or time requirements for the identification of research that meets the scope of the Policy, comments indicated that it was not clear whether and how a PI should continue to consider the dual use potential of his or her work or whether a PI should ever re-examine work that has been previously determined by the IRE to not meet the definition of DURC. Twelve of the 16 comments addressing this topic agreed that some form of ongoing review by the PI and/or the dual use review entity was reasonable. However, there were concerns regarding the increased burden that ongoing or periodic review would have

on institutions, in particular the interpretations that this ongoing review would involve monitoring in perpetuity all research that meets the scope of the Policy. In response to these comments, Section 7.1.A of the final Policy includes revisions that require PIs to notify the IRE as soon as, (1) his or her research involves one or more of the agents or toxins listed in Section 6.2.1; (2) his or her research with one or more of the agents or toxins listed in Section 6.2.1 of the Policy also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven effects listed in Section 6.2.2 of the Policy; or (3) his or her research that is within the scope of Section 6.2 of the Policy may meet the definition of DURC (as defined in Section 4 of the Policy).

## **Section 7.2. Responsibilities of USG-Funded Research Institutions**

**Section 7.2.B.** Section 7.2 of the final Policy details the oversight process and the roles and responsibilities of research institutions (Federal and non-Federal) that receive USG funds for life sciences research and that conduct or sponsor research with any of the 15 agents or toxins listed in Section 6.2.1 of the final Policy. Public comment was requested on ways to optimize the relationship between the *March 2012 DURC Policy* and the proposed *Policy for Institutional DURC Oversight*. Nine comments were received related to the requirements in both policies to review research for DURC potential and develop and implement risk mitigation plans for any identified DURC. Four of these comments noted the potential for duplicate reviews for research that is found to be DURC by both the IRE (per the final *Policy for Institutional DURC Oversight*) and the Federal funding agency (per the *March 2012 DURC Policy*). Likewise, four of these comments noted that both policies require the development of risk mitigation plans for any identified DURC and that this could lead to a single DURC project with two risk mitigation plans.

In an effort to reduce burden for the implementing institutions, the final Policy includes revisions that indicate that research that has already been determined to be DURC under the *March 2012 DURC Policy* and is already being conducted under a risk mitigation plan does not require the development of a new risk mitigation plan. In addition, any research that has already been determined to be DURC under the *March 2012 DURC Policy*, and for which a risk mitigation plan has already been developed, is not required to undergo the review steps outlined in Sections 7.2.B.i-vi. However, the institutions will remain responsible for ensuring that the risk mitigation plan is implemented and kept up-to-date, that the PIs continue to conduct ongoing assessments of their research, and that the risk mitigation plan undergoes annual review by the IRE (described below).

**Section 7.2.B.iii** of the final Policy includes revisions to clarify that the IRE should include the PI in its review activities, as appropriate, and that any research that has been determined by an institution to be DURC should not be conducted until an approved risk mitigation plan has been implemented.

**Section 7.2.B.iv** of the final Policy describes the first reporting requirement of institutions regarding oversight of DURC: within 30 calendar days of the institutional review of the research for DURC potential, the institution must notify the USG of any research that falls within the scope of 6.2, including whether the research meets or does not meet the definition of DURC. Revisions included in the final Policy also detail the necessary information to include in this initial 30-day notification: the grant or contract number related to the research (if the research is funded by the USG); the name(s) of PI(s); the name(s) of the applicable agent(s) listed in Section 6.2.1 of the Policy; and a description of why the research is deemed to produce one or more of the experimental effects listed in Section 6.2.2 of the Policy. For research that is determined by the IRE to meet the definition of DURC, the notification

should also include: the name of the investigator (if different from the PI) responsible for the performance of the DURC; and a description of the IRE's basis for its determination.

**Section 7.2.B.v-vi.** These sections of the final Policy regard the institution working together with the USG funding agency to develop a risk mitigation plan for research that has been determined by the institution to be DURC. In order to clarify this process, the final Policy includes revisions that require the institution to submit a *draft* risk mitigation plan to the USG funding agency within 90 calendar days of the IRE's determination that the research is DURC. In turn, the USG funding agency is required to finalize and approve the risk mitigation plan within 60 calendar days of receipt of the draft plan.

**Section 7.2.B.viii-ix.** In order to clarify and streamline the requirements for periodic review by IREs of the risk mitigation plans developed in response to determinations of DURC, the final *Policy for Institutional DURC Oversight* includes revisions that require IREs to review, at least annually, all active risk mitigation plans and modify them, as needed. This annual review should apply to all risk mitigation plans for DURC taking place at the institution, regardless of whether the DURC was identified per the final *Policy for Institutional DURC Oversight* or the *March 2012 DURC Policy*. The review of risk mitigation plans would likely include a review of the DURC itself, and may result in a change in the DURC status of the research (e.g., the research no longer meets the definition of DURC). Therefore, the final Policy also includes revisions that require IREs to notify, within 30 calendar days, the appropriate USG agency of any change in the status of a DURC-designated project at the institution, and details of any changes to risk mitigation plans, which need to be approved by the funding agency.

**Review of research proposals.** Thirteen comments were received in response to the request for feedback on whether research institutions should review life sciences research proposals for DURC issues

prior to their submission to a funding agency. Eight of the comments noted that fewer proposals are funded than are submitted, and thus a requirement for institutional reviews of proposals before funding is secured could result in a waste in effort and an unnecessary burden upon the institution.

In response to these comments, references to the institutional or IRE review of research proposals for DURC concerns prior to submission to a funding agency have been removed. However, it should be noted that institutions that conduct Federally-funded life sciences research are required, at the time of application for USG funds for life sciences research, to provide certification to the USG funding agency or agencies that the institution is in full compliance with all aspects of the Policy or will be at the time the research is initiated. In addition, the *Policy for Institutional DURC Oversight* requires PIs to identify any and all research involving one or more of the 15 listed agents and refer such research to the IRE, along with the PIs assessment of the applicability of the listed experimental effects. Thus, institutions will have a process in place for reviewing research for dual use concerns before the research is initiated, and this review must be done by the time this research begins.

Comments on the proposed Policy also indicated that guidance was needed for institutions and IREs to meet the review and reporting requirements set forth in Section 7.2.B. To assist institutions and their IREs, Section C of the *Companion Guide* contains more information on the reporting requirements for institutions with respect to findings of DURC. Also, Section D of the *Companion Guide* contains guidance and tools to assist IRE's in the drafting of risk mitigation plans for DURC.

**Section 7.2.D.** The proposed *Policy for Institutional DURC Oversight* described the role of an Institutional Contact for Dual Use Research (ICDUR), who is designated by the institution to serve as a point of contact for questions regarding compliance with and implementation of the requirements for the

oversight of research that falls within the scope of and/or meets the definition of DURC. When questions arise regarding compliance or implementation of the final Policy or the *March 2012 DURC Policy*, the assessment of DURC, or the development of risk mitigation plans, the ICDUR also serves as the liaison (as necessary) between the institution and the relevant program officers at the Federal agencies.

Comments were solicited regarding the feasibility of a single individual serving in the capacity of the ICDUR. Nine of the thirteen comments were supportive of the ICDUR's role, with two comments voicing concerns about the expertise and training needed for performing the role of the ICDUR. Based on the comments received concerning the role and expertise of the ICDUR, the final Policy clarifies that the ICDUR is not expected to be able to answer all DURC-related questions, but rather would serve as the institutional point of contact for questions and would ensure that all questions are adequately addressed by the appropriate subject matter experts. Furthermore, it is at the discretion of the institution to decide whether the position of ICDUR should be a new full-time position or whether the responsibilities of the ICDUR should be assigned to an extant institutional staff member or official.

**Section 7.2.E.** The final *Policy for Institutional DURC Oversight* details the responsibility of institutions subject to the Policy to establish an IRE, describes the range of mechanisms available to institutions in meeting this requirement, and details the required attributes of an IRE. Comments were requested on how DURC oversight could be usefully integrated with other existing institutional oversight processes in order to reduce duplication and burdens on institutions, as well as the feasibility, benefits, and limitations of using an institution's Institutional Biosafety Committee (IBC) to conduct the DURC institutional review process.

Twelve of the nineteen comments received on the topic of utilizing extant IBCs for dual use reviews posited that integration of DURC review with existing IBC processes would be less of a burden for the institution than establishing a new entity for the sole purpose of conducting DURC reviews. These institutions noted that, because some IBCs already conduct some form of review for dual use concerns, they are familiar with the concept already. In addition, the commenting institutions noted that using an extant body would eliminate a duplicative process of standing up yet another entity for a similar submission and review process. A few (four) of the respondents either opposed the use of the IBC for DURC review or requested more information on the process. These comments described potential challenges to using the IBC for dual use reviews, including that review of research for dual use concerns would be an entirely new role for the IBC and that committee members may not have the expertise to conduct such reviews. Also, the time required to review research projects could increase significantly for IBCs, reducing the efficiency of both the recombinant DNA and dual use reviews. Many comments were also concerned with the ability of IREs to recognize and assess the risks associated with DURC. A few comments noted that institutions may not have the expertise required to identify DURC and that the consistency of DURC reviews among institutions may vary considerably. Other comments requested more guidance and tools for the institution and its IRE to assist in the review and oversight processes.

To address the comments and concerns on the composition and expertise of the IRE, the final Policy clarifies that: the IRE is to be composed of no fewer than five members; the IRE membership should be empowered by the institution to execute the actions listed in Sections 7.2.B.i-iii, v, and viii, of the final Policy; the IRE should include members that understand biosafety and biosecurity considerations; and the IRE may include as a member or as a consultant at least one individual knowledgeable of the institution's policies and procedures. No changes were made regarding the range of mechanisms available to institutions in fulfilling the requirement to establish an IRE; the final Policy

retains the flexibility for institutions to create or designate the review entity best suited for their needs, as long as the review entity is appropriately constituted (per Section 7.2.E.ii-iv) to meet the requirements of the final Policy. In addition, guidance on the establishment of an IRE has been provided in the *Companion Guide* and training materials have been developed to assist institutions and their IREs in implementing the requirements of the final Policy.

Of note, the final Policy identifies resources for institutions with questions regarding DURC reviews or oversight. The final Policy describes the USG's responsibility to provide guidance to institutions on the sharing of DURC research products and on the communication of DURC, as well as convene advisory bodies such as the National Science Advisory Board for Biosecurity (NSABB), when necessary, to develop recommendations on particularly complex cases of DURC. In addition, per Section 8.B, institutions may, with the participation of the designated ICDUR, consult with the USG department or agency that is funding the research (or in the case of non-USG funded research, with the NIH or with the USG funding agency designated by the NIH) for advice on matters related to DURC.

**Section 7.2.F. Retention of records.** The proposed *Policy for Institutional DURC Oversight* required institutions to maintain records of institutional DURC reviews, risk mitigation plans, and personnel training on dual use research for three years. Comments were solicited regarding the appropriate amount of time that institutions should be required to retain such records. Twelve comments were received on this topic. Nine recommended that records be retained for or beyond the period of time of the research grant or contract. Five of the comments indicated that records should be retained, at a minimum, for the length of the grant or contract period and then three additional years following project termination or completion. Two comments indicated that indefinite records retention was too burdensome for institutions. The comments also indicated that while research institutions may have different records

retention requirements, these requirements are generally record-specific; that is, each type of record may have its own retention schedule and requirement. Three comments considered the records retention requirements of the *Policy for Institutional DURC Oversight* to be repetitive and unnecessary considering that the laboratories conducting research subject to the *Policy for Institutional DURC Oversight* are also complying with biological select agents and toxins (BSAT) related record-keeping requirements, Occupational Safety and Health Administration regulations, Environmental Protection Agency regulations, and biosafety-related requirements – some of which have record retention requirements that exceed the length of time indicated in the proposed Policy. These comments recommended that the USG harmonize the recordkeeping requirements.

The final Policy includes revisions that require institutions to maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation. This revision accommodates the period of performance for most life sciences research grants and contracts.

**Section 7.2.H.** The final *Policy for Institutional DURC Oversight* includes revisions to clarify that it is the institution, not the IRE, that is responsible for institutional compliance with the final Policy. While institutions are required to empower their IRE to execute the requirements listed in Section 7.2.B.i-iii, v, and viii, the responsibility to ensure compliance with the final Policy and with approved risk mitigation plans, as well as report instances of non-compliance, rests with the institution. The final Policy incorporates revisions to clarify these points. As noted earlier, language regarding compliance with the final Policy has been moved to a new section (Section 6.3).

**Section 7.2.K. Accessibility of Institutional Review Procedures.** The proposed *Policy for Institutional DURC Oversight* required IREs to make their procedures for reviewing life sciences research for dual use potential accessible to the public. Further, it stipulated that the posted policies of the institution should include an overview of the institution's procedures or review process, but should not include details of particular cases or the minutes of the DURC review entity's proceedings. The final Policy includes revisions to clarify that institutions should make documentation of their DURC review process available to the public upon request, as consistent with applicable law. In addition, the final Policy has been updated to indicate that the provision of DURC review procedures is an institutional responsibility that may be delegated to IREs.

**7.2.L. Certification of compliance.** The proposed *Policy for Institutional DURC Oversight* required institutions to provide, on an annual basis, a formal assurance to the appropriate Federal funding agency or agencies that the institution is in compliance with all aspects of the Policy. Two comments addressed the process for providing institutional assurances of compliance with the Policy. Suggestions for reducing burden associated with providing assurances included lengthening the period of time between assurances and allowing institutions to file a single assurance with a single entity (as is the case for the Common Rule) rather than requiring institutions to provide an assurance to each Federal funding agency that they work with.

The final Policy contains revisions clarifying that certification of compliance must be provided by an institution at the time of seeking funding for life sciences research, but no sooner than the effective date of the final Policy. Each USG funding agency will be implementing the certification requirement for applicants and grantees according to their own agency policies. More information and guidance on meeting the institutional requirement to provide certification of compliance with the *Policy for*

*Institutional DURC Oversight* can be obtained in the grants and contracting policies of the funding agency.

**Notes at the end of 7.2.**

**DURC research at multiple institutions.** The proposed *Policy for Institutional DURC Oversight* noted that there will be situations where a PI is conducting potential DURC at multiple institutions and proposed that it should be the purview of each institution to review these projects and, if appropriate, develop and implement a risk mitigation plan. Examples of DURC projects involving more than one institution include cases where the DURC is a collaboration between PIs at different institutions or when the DURC is undertaken by a single PI who maintains laboratories at more than one institution. Comments were requested regarding whether each institution participating in a multi-site DURC project should have oversight of their portion of the projects and, if DURC is being conducted at their institution, develop and implement their own risk mitigation plans, or whether the primary institution should have the responsibility for meeting the requirements for oversight of DURC.

Twelve comments were received related to the oversight of DURC taking place at multiple institutions. Seven of the comments expressed the view that each institution conducting DURC should be responsible for the assessment of its research for DURC potential, and, in cases where DURC is determined, develop and implement a risk mitigation plan. Comments differed, however, on how institutions should work together to coordinate the oversight responsibilities of the DURC. Two comments suggested that in cases of multiple PIs (and their institutions) collaborating on a single DURC project, the institutions of the collaborating investigators should report any findings of DURC to a single, primary institution. Conversely, another comment stated that DURC assessment should be a

responsibility of the primary or lead institution in the DURC collaboration, but that the individual collaborating institutions should be responsible for risk mitigation plan development and implementation of their portion of the project. Some (five) of the comments were concerned with how differences in institutional DURC assessments and mitigation plans should be handled, how these differences are arbitrated, and how the risk mitigation plan(s) should be implemented in cases of differing institutional resources and capabilities.

The oversight of research that falls within the scope and applicability of the final Policy should be consistent, regardless of whether the research is undertaken by a single investigator at a single institution, by a single investigator holding multiple research positions at different institutions, or by multiple investigators collaborating across institutions. When DURC research is undertaken at multiple institutions, these institutions should work together to ensure that DURC oversight, including the DURC reviews and any resulting risk mitigation plans, is implemented consistently across the collaborating entities. Consequently, in the final Policy, the note at the conclusion of Section 7.2 includes revisions to clarify that in the case of DURC collaborations involving multiple institutions, the primary institution (i.e., the institution in receipt of the grant or contract from the USG funding agency) is responsible for notifying the funding agency of research that falls within the scope of the Policy and, if that research is determined to be DURC, providing copies of each collaborating institution's risk mitigation plan. Furthermore, the primary institution should ensure that DURC oversight is consistently applied by all entities participating in the collaboration.

The final Policy includes an additional note in this section regarding cases in which a Federal department or agency simply passes through funding from another Federal department or agency to support life sciences research at an institution that conducts or sponsors research involving any of the

agents listed in Section 6.2.1. In such cases, the agency originally providing the funding shall be considered the USG funding agency, and the ultimate recipient of the funds shall be considered the institution, and respectively shall fulfill the requirements expected of each under this Policy.

### **Section 7.3. Responsibilities of USG Funding Agencies**

In order to facilitate timely finalization of risk mitigation plans drafted by the IRE (per Section 7.2.B.v) and submitted by institutions (per Section 7.2.B.vi), the final *Policy for Institutional DURC Oversight* requires the appropriate USG agencies to provide an initial response to institutions within 30 calendar days and finalize the plan within 60 calendar days of receipt of the draft plan. This change is, in part, due to two comments received that suggested a specified time frame for USG funding agencies to respond.

### **Section 8. Resources for Institutional Oversight of DURC**

The final Policy contains no revisions to Section 8. However, as referenced in Section III of this Notice, Section 8.A of the Policy describes an implementation guide (i.e., a “*compendium of tools*”) for use with both the *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*. Comments were requested on the sufficiency of the tools and guidance material, and approximately one-third of the 26 comments received indicated the list to be sufficient. However, many more comments included suggestions of additional tools and how tools should be developed. These suggestions include provision of real or hypothetical case studies illustrating the DURC assessment process, provision of example or template risk mitigation plans, and additional guidance for interpreting the seven experimental effects enumerated in the Policy. Comments received in response to the proposed Policy were helpful in developing and revising the guide’s components, including: a tool to assist PIs and IREs in assessing the applicability of the listed experimental effects; points to consider in the assessment of risks and benefits;

guidance on developing a risk mitigation plan for IRE-identified DURC; and guidance regarding the responsible communication of DURC.

The compendium of implementation tools is titled *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: Companion Guide to the USG Policies for Oversight of Life Sciences Dual Use Research of Concern (Companion Guide)*, and is posted on the U.S. Department of Health and Human Services Science Safety Security (S3) Web site: <http://www.phe.gov/s3/dualuse>. Use of the *Companion Guide* by PIs, institutions, and Institutional Review Entities (IREs) is, however, not a requirement of the *Policy for Institutional DURC Oversight* or the *March 2012 DURC Policy*.

---

Cristin A. Dorgelo,  
*Chief of Staff,*  
*Office of Science and Technology Policy.*

Billing Code – 3270-F4

[FR Doc. 2014-22770 Filed 09/24/2014 at 8:45 am; Publication Date: 09/25/2014]